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Of Counsel for Plaintiff Horizon Medicines LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON MEDICINES LLC, *Plaintiff,* v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., *Defendants.*	CIVIL ACTION No. Document Filed Electronically **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Horizon Medicines LLC ("Plaintiff" or "Horizon"), by its undersigned attorneys, brings this action against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Defendants" or "Teva"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendants' filing of an

Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiff's pharmaceutical product DUEXIS® (Ibuprofen and Famotidine Tablets) 800 mg/26.6 mg ("DUEXIS®") prior to the expiration of United States Patent Nos. 8,067,033 ("the '033 patent"), 8,067,451 ("the '451 patent"), 8,309,127 ("the '127 patent"), 8,318,202 ("the '202 patent"), 8,449,910 ("the '910 patent"), and 8,501,228 ("the '228 patent") (collectively, the "Asserted Patents"), which cover DUEXIS® and its use.

THE PARTIES

2. Plaintiff Horizon Medicines LLC is a corporation operating and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Rd, Lake Forest, Illinois 60045.

3. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation operating and existing under the laws of the Delaware, having principal places of business at 400 Interpace Pkwy #3, Parsippany, New Jersey 07054 and 425 Privet Road, Horsham, Pennsylvania 19044.

4. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. is a corporation operating and existing under the laws of Israel, with principal places of business at 145 Brandywine Pkwy, West Chester, PA 19380 and 2945 W. Corporate Lakes Blvd, Weston, Florida 33331.

5. On information and belief, Teva Pharmaceuticals USA, Inc. is a subsidiary of Teva Pharmaceuticals Industries Ltd.

6. On information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through their own actions.

7. On information and belief, Defendants participated in the research and development, and the preparation and filing, of ANDA No. 211278 ("the Teva ANDA")

for ibuprofen and famotidine tablets ("the Teva Product"), continue to seek FDA approval of that application, and intend to commercially manufacture, market, offer for sale and sell the Teva Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Teva's ANDA.

8. On information and belief, should the Teva ANDA be finally approved by FDA, Defendants will sell, offer for sale, and distribute the Teva Product throughout the United States, including within this judicial district.

9. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have admitted to, consented to, or have not contested, the jurisdiction of this Court in numerous prior District of New Jersey actions, e.g.: *Indivior Inc. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:17-cv-07115; *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:16-cv-07721; *Eisai Co., Ltd. et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:05-cv-05727; *Novartis Pharms. Corp. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:05-cv-01887; *Altana Pharma AG et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd.*, Civil Action No. 2:04-cv-02355.

10. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have availed themselves of the rights, benefits, and privileges of this Court by filing lawsuits in numerous prior District of New Jersey actions, e.g.: *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 3:17-cv-00517; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Sandoz Inc. et al.*, Civil Action No. 3:17-cv-00275; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 2:15-cv-00471; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Synthon Pharms., Inc. et al.*, Civil Action No. 2:15-cv-00472; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 3:14-cv-05672; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Apotex, Inc. et al.*, Civil Action No. 3:07-cv-05514; *Teva Pharm. Industries*

Ltd. and Teva Pharms. USA, Inc. v. Cadila Pharms. Ltd., Civil Action No. 3:07-cv-02912; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cobalt Pharms., Inc. et al.*, Civil Action No. 2:07-cv-01690; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:07-cv-00621; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Andrx Corp.*, Civil Action No. 2:07-cv-00244; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cipla Ltd. et al.*, Civil Action No. 2:07-cv-00240.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that Defendants should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court (*e.g.*, by assertion of claims and counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of drug products throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of drug products, including Teva products, within this judicial district, and through their intent to market and sell the Teva Product, if approved, to residents of this judicial district.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

14. On November 29, 2011, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '033 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

15. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '033 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '033 patent is attached hereto as Exhibit A.

16. On November 29, 2011, the USPTO duly and legally issued the '451 patent entitled "Methods and Medicaments for Administration of Ibuprofen."

17. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '451 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '451 patent is attached hereto as Exhibit B.

18. On November 13, 2012, the USPTO duly and legally issued the '127 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

19. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '127 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '127 patent is attached hereto as Exhibit C.

20. On November 27, 2012, the USPTO duly and legally issued the ’202 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

21. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the ’202 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’202 patent is attached hereto as Exhibit D.

22. On May 28, 2013, the USPTO duly and legally issued the ’910 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

23. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the ’910 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’910 patent is attached hereto as Exhibit E.

24. On August 6, 2013, the USPTO duly and legally issued the ’228 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

25. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the ’228 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’228 patent is attached hereto as Exhibit F.

DUEXIS®

26. Horizon Medicines LLC is the owner of FDA-approved New Drug Application No. 025519 (“the DUEXIS® NDA”) for ibuprofen and famotidine tablets

(DUEXIS®), which is sold in the U.S. under the trade name DUEXIS®, and which is sold by Horizon Medicines LLC.

27. The DUEXIS® tablet is currently approved by the FDA for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patents who are taking ibuprofen for those indications.

28. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '033, '451, '127, '202, '910 and '228 patents are currently listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the DUEXIS® NDA.

29. The '033, '451, '127, '202, '910 and '228 patents cover DUEXIS® and FDA-approved uses thereof.

TEVA'S ANDA

30. On information and belief, Teva submitted the Teva ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market ibuprofen and famotidine tablets, 800 mg/26.6 mg. On information and belief, the Teva ANDA seeks approval to market the Teva Product for treatment of ibuprofen-responsive disorders with reduction of risk of gastro-intestinal problems.

31. On information and belief, the Teva ANDA refers to and relies upon the DUEXIS® NDA and contains data that, according to Teva, demonstrate the bioequivalence of the Teva Product and DUEXIS®.

32. Plaintiff received from Teva a letter, dated September 26, 2018 (the "Teva Notification"), stating that Teva had included a certification in the Teva ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the '033, '451, '127, '202, '910 and '228 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Teva Product ("the Paragraph IV Certification").

33. The Teva Notification states that the Teva ANDA seeks approval to engage in the commercial manufacture, use or sale of ibuprofen and famotidine tablets, 800 mg/26.6 mg before the expiration of the ’033, ’451, ’127, ’202, ’910 and ’228 patents.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,033

34. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-33 of this Complaint.

35. The ’033 patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

36. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the ’033 patent expires, Defendants have infringed the ’033 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

37. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’033 patent, also would infringe, either literally or under the doctrine of equivalents, the ’033 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’033 patent.

39. Upon information and belief, Defendants had actual and constructive notice of the ’033 patent as of its issue date, and Defendants’ infringement of the ’033 patent is willful.

40. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’033 patent, or any later expiration of any exclusivity or extension of the ’033 patent to which Plaintiff or the

patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiff or the patent may become entitled.

41. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '033 patent by Defendants, together with interest and costs.

42. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '033 patent.

43. Plaintiff has no adequate remedy at law.

44. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,451

45. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-44 of this Complaint.

46. The '451 patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

47. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation

of the Teva Product, prior to date on which the ’451 patent expires, Defendants have infringed the ’451 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

48. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’451 patent, also would infringe, either literally or under the doctrine of equivalents, the ’451 patent under 35 U.S.C. § 271(a), (b) and/or (c).

49. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’451 patent.

50. Upon information and belief, Defendants had actual and constructive notice of the ’451 patent as of its issue date, and Defendants’ infringement of the ’451 patent is willful.

51. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled.

52. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a

reasonable royalty and/or lost profits for the use made of the invention of the ’451 patent by Defendants, together with interest and costs.

53. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’451 patent.

54. Plaintiff has no adequate remedy at law.

55. This case is exceptional, and Plaintiff is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,309,127

56. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-55 of this Complaint.

57. The ’127 patent issued on November 13, 2012, and will expire no earlier than July 18, 2026.

58. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Teva Product, prior to date on which the ’127 patent expires, Defendants have infringed the ’127 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

59. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’127 patent, also would infringe, either literally or under the doctrine of equivalents, the ’127 patent under 35 U.S.C. § 271(a), (b) and/or (c).

60. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’127 patent.

61. Upon information and belief, Defendants had actual and constructive notice of the '127 patent as of its issue date, and Defendants' infringement of the '127 patent is willful.

62. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled.

63. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '127 patent by Defendants, together with interest and costs.

64. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '127 patent.

65. Plaintiff has no adequate remedy at law.

66. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,318,202

67. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-66 of this Complaint.

68. The ’202 patent issued on November 27, 2012, and will expire no earlier than July 18, 2026.

69. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale of importation of the Teva Product, prior to date on which the ’202 patent expires, Defendants have infringed the ’202 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

70. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’202 patent, also would infringe, either literally or under the doctrine of equivalents the ’202 patent under 35 U.S.C. § 271(a), (b) and/or (c).

71. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’202 patent.

72. Upon information and belief, Defendants had actual and constructive notice of the ’202 patent as of its issue date, and Defendants’ infringement of the ’202 patent is willful.

73. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’202 patent, or any later expiration of any exclusivity or extension of the ’202 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the ’202 patent, or any later expiration of any exclusivity or extension of the ’202 patent to which Plaintiff or the

patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '202 patent, or any later expiration of any exclusivity or extension of the '202 patent to which Plaintiff or the patent may become entitled.

74. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '202 patent by Defendants, together with interest and costs.

75. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '202 patent.

76. Plaintiff has no adequate remedy at law.

77. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,449,910

78. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-77 of this Complaint.

79. The '910 patent issued on May 28, 2013, and will expire no earlier than July 18, 2026.

80. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to the date on which the '910 patent expires, Defendants have infringed the '910 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

81. Defendants' commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United

States, during the term of the ’910 patent, also would infringe, either literally or under the doctrine of equivalents, the ’910 patent under 35 U.S.C. § 271(a), (b) and/or (c).

82. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’910 patent.

83. Upon information and belief, Defendants had actual and constructive notice of the ’910 patent as of its issue date, and Defendants’ infringement of the ’910 patent is willful.

84. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’910 patent, or any later expiration of any exclusivity or extension of the ’910 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the ’910 patent, or any later expiration of any exclusivity or extension of the ’910 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the ’910 patent, or any later expiration of any exclusivity or extension of the ’910 patent to which Plaintiff or the patent may become entitled.

85. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the ’910 patent by Defendants, together with interest and costs.

86. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’910 patent.

87. Plaintiff has no adequate remedy at law.

88. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,501,228

89. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-82 of this Complaint.

90. The '228 patent issued on August 6, 2013, and will expire no earlier than July 18, 2026.

91. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to the date on which the '228 patent expires, Defendants have infringed the '228 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

92. Defendants' commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the '228 patent, also would infringe, either literally or under the doctrine of equivalents, the '228 patent under 35 U.S.C. § 271(a), (b) and/or (c).

93. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the '228 patent.

94. Upon information and belief, Defendants had actual and constructive notice of the '228 patent as of its issue date, and Defendants' infringement of the '228 patent is willful.

95. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration of the '228 patent, or any later expiration of any exclusivity or extension of the '228 patent to which Plaintiff or the

patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '228 patent, or any later expiration of any exclusivity or extension of the '228 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '228 patent, or any later expiration of any exclusivity or extension of the '228 patent to which Plaintiff or the patent may become entitled.

96. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '228 patent by Defendants, together with interest and costs.

97. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '228 patent.

98. Plaintiff has no adequate remedy at law.

99. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a judgment in its favor and against Defendants, and respectfully requests the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of the Asserted Patents;

B. A declaration that Defendants' commercial manufacture, use, offer for sale, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, prior to the expiration of the Asserted Patents, including any extensions, would constitute an act of infringement of the Asserted Patents;

C. If Defendants commercially manufacture, use, offer to sell, or sell the Teva Product within the United States, or import the Teva Product into the United States, prior to the expiration of the Asserted Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

D. That Plaintiff be awarded damages adequate to compensate it for Defendants' past, present, and/or future infringement of the Asserted Patents, said damages being no less than a reasonable royalty and/or lost profits together with any pre-judgment interest and post-judgment interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284;

E. That an accounting be performed to determine the damages to be awarded to Plaintiff as a result of Defendants' infringing activities, including an accounting for infringing sales not presented at trial and an award of additional damages for any such infringing sales;

F. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Teva ANDA shall be a date not earlier than the expiration of the Asserted Patents, inclusive of any extensions;

G. That a preliminary and/or permanent injunction be issued enjoining Defendants, and their affiliates, officers, agents, employees, attorneys, and all persons in active concert of participation with and of them, from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the Asserted Patents, inclusive of any extensions;

H. A judgment finding that Defendants' infringement of the Asserted Patents was deliberate and willful;

I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

J. Costs and expenses in this action; and

K. Such other and further relief as the Court deems just and proper.

Date: July 2, 2020

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Of Counsel for Plaintiff Horizon Medicines LLC

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff Horizon Medicines LLC, by its undersigned attorneys, hereby certifies pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending action involving and/or relating to Horizon Medicines LLC, DUEXIS®, and the Asserted Patents: *Horizon Medicines LLC v. Alkem Laboratories Ltd.*, Civil Action No. 1:18-cv-01014-RGA (D. Del.).

Date: July 2, 2020

s/ John E. Flaherty

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